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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/458,533	LI ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36 and 38-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36 and 38-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. At page 6 of the response received 14 April 2003, applicant states that "Claims 36-54 are pending." The amendment of 14 April 2003 called for the cancellation of claims 28-35 and 37. Accordingly, claims 36 and 38-54 are currently pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 36 and 38-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As presently worded, the claimed apparatus can comprise virtually any "conjugated polymer" and that the "conjugated polymer" can be of virtually any thickness. A review of the disclosure fails to find an adequate written description of the genera of conjugated polymers and that the apparatus is to comprise same and at any thickness. In support of this position, attention is directed to page 15, last paragraph, bridging to page 16, reproduced below.

In some embodiments, oligonucleotide probes are immobilized on the microelectrodes of the apparatus of the present invention using a neutral layer between the oligonucleotides and the microelectrodes. In a preferred embodiment, this layer comprises neutral polypyrrole. In alternative embodiments, this layer comprises such substances as polythiophene, polyaniline, polyfuran, polypyridine, polycarbazole, polyphenylene, poly(phenylenvinylene), polyfluorene, polyindole, their derivatives, their copolymers, and combinations thereof. The layer is preferably at least about 0.001 to 50 μm thick, more preferably at least about 0.01 to 10 μm thick and most preferably at least about 0.5 μm thick.

4. While the disclosure does indicate that applicant had contemplated the use of a variety of polymers, only neutral polypyrrole is described in sufficient detail so to reasonably suggest that applicant possessed an invention that comprised said polymer, and then the apparatus comprised said polymer within the contemplated and described range.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 36 and 38-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al., in view of Hashimoto et al., Guttman et al., and Anderson et al.

9. Heller et al., disclose an apparatus comprising microelectrodes to be used in the detection of molecular interactions between an immobilized oligonucleotide probe and a target nucleic acid molecule. Column 12 discloses that electrodes may be comprised of silver, platinum as well as alternative metals (lines 55-59). The aspect of having the electrodes insulated through the use of materials such as SiO₂ is disclosed at column 13, first full paragraph. The aspect of having gel pads, such as polyacrylamide gel, incorporated into the device is disclosed at column 15, second paragraph. The aspect of using the apparatus to carry out a variety of multi-step and/or multiplex reactions and procedures, including nucleic acid hybridization procedures, is disclosed at columns 16-19. At column 19 there is disclosed the incorporation of detection means.

10. Heller et al., do not disclose the incorporation of detection means, lithium acetate, or the coating of electrodes with a polymer such as polypyrrole.

11. Hashimoto et al., column 10, fourth full paragraph, disclose immobilizing nucleic acid probes to an electrode through the use of films. As seen therein, a variety of suitable polymers, including polypyrrole, are explicitly disclosed. Motivation for coupling the probe to the electrode via a film is found in the following paragraph where it is disclosed that probes can be immobilized in higher density and can be immobilized more stably when films are used.

12. Hashimoto et al., does not disclose using lithium acetate.

13. Guttman et al., abstract and column 3, teach the use of an acetate buffer in combination with electrodes and electrophoretic methods.

14. Neither Heller et al., nor Guttman et al., disclose the use of lithium acetate at a concentration of 0.1 M. It is noted that claim 12 defines the concentration of lithium acetate as being (about 0.1 M.” The term “about” is considered to encompass values above and below the identified point. Further, the limit of what constitutes ‘about’ has not been defined and is therefore open to consideration. Accordingly, while neither prior art reference discloses this specific data point, the selection of one concentration of reactants over another concentration of reactants is considered to be, in the absence of convincing evidence to the contrary, the result of routine optimization.

15. Anderson et al., columns 60-61, disclose the incorporation of detection means whereby impedance of a target nucleic acid is measured between electrodes. Such a teaching meets the limitation of claims 36 and 37 wherein part d) a detector is connected to the microelectrodes.

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16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the acetate buffer disclosed by Guttman et al., with the device of Heller et al., where probes were immobilized to the electrode via a film as disclosed by Hashimoto et al., as Guttman et al., teach at column 6 that the buffer and its pH are important, as is the presence of molecular sieving medium, and that the use of their buffer provides improved quantitative data. It would have also been obvious to said ordinary artisan to have incorporated the detection means of measuring the impedance of a target nucleic acid as disclosed by Anderson et al. as Anderson et al., teaches explicitly of using impedance measurements to detect nucleic acids. Accordingly, and in the absence of convincing evidence to the contrary, the ordinary artisan would have been both motivated and would have had a reasonable expectation of success as the state of the art had advanced to the point that it was quite reproducible.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

21. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS